

REMARKS

Reconsideration of this application is respectfully requested. Claims 1-18 and 39 as amended remain in the case.

Initially, the Examiner's comments regarding the finality of the requirement for restriction are noted, and Applicants, while maintaining their traversal, will proceed with the prosecution of the claims of Group I herein.

The Examiner has objected to the abstract on the basis that it is formatted in multiple paragraphs. The abstract has been amended as per the above, to delete the line and paragraph spaces, and withdrawal of the objection thereto is believed to be in order, and is requested.

The disclosure has been objected to on the basis that certain portions of the specification lack reference to corresponding Sequence ID Numbers. Some of the sequence information has been added by this amendment, and the remainder of the specification will be reviewed to assure that all passages are in conformity. Accordingly, any further amendments that are deemed necessary will be made in response to the next communication from the Examiner.

Claims 9, 12, 14-18 and 39 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite. Claims 12 and 39 have been amended to clarify the meaning of the language objected to by the Examiner, and the revision of Claim 1 is believed to provide the antecedent basis sought with respect to Claim 12. With respect to Claims 14-18, Applicants submit that the characteristic of immunogenicity is a meaningful limitation, particularly when considered in the light of the showings in *eg.* Examples 3 and following, the protective effect achieved with the truncates of the present invention is indeed a function of their structure, and more particularly, is surprising given that the arbitrary deletion of choline binding domains reveals a molecule wherein the N terminal sequence demonstrates this surprising activity. On this basis alone, the description of the polypeptides of the present invention as immunogenic must be given weight and not disregarded as of no patentable significance herein. Accordingly, reconsideration and withdrawal of the above grounds of rejection are believed to be in order and are requested.

Claims 7-9 have been rejected under 35 U.S.C. §112, first paragraph, on the basis that they contain subject matter not described in the specification in a manner that enables the artisan to practice the claimed invention. Applicants take issue with this rejection and submit

that it should be withdrawn.

The Examiner contends that the present teachings are limited in their scope to the N terminal fragment discussed on page 64, however, it is Applicants' position that the teachings presented therein are applicable to all of the polypeptides encompassed by the present claims. Initially, the polypeptides are of common origin and as such, share certain characteristics, among them, their propensity for conformation in the natural state. Yet further, it is this natural or native state that is being advanced as a standard for identification and distinction of the present polypeptides from those that might be *eg.* synthetically prepared. One of the characteristics of the present invention is that the claimed polypeptide truncates retain their native conformation despite the fact that they result from the arbitrary and predetermined severance from the full length protein. Even the attempt during such an exercise to retain native conformation is subject to the uncertainty of outcome and, more importantly, corresponding uncertainty as to whether the resulting fragment will demonstrate the desired activity attributed to the full length material.

It is therefore, the retention of native conformation by the truncate, that can be compared to the corresponding region of the full length native material for fidelity of architecture, that constitutes the salient feature set forth herein. While one may speculate as to the possible variation in tertiary structure, it is the demonstration of any such structure that is a significant herein, and that is accordingly meritorious of claim denomination.

Moreover, the art is possessed of numerous contemporary techniques for the facile and rapid determination of tertiary structures. Advances in X-ray crystallography and proteomics have yielded numerous strategies that researchers now employ to rapidly comprehend tertiary structure and accurately predict activity and associated physicochemical characteristics, so that the statement of assessment of tertiary structure without more, it is submitted, would suffice in the context of contemporary research technology.

Notwithstanding this, it should be noted that Applicants believe that they have fulfilled their duty to provide sufficient descriptive and enabling support by the teachings referred to by the Examiner in this rejection. Thus, Applicants believe that the Examiner's concerns as to the potential shortcomings of the present specification as a teaching document, are unwarranted, and that withdrawal of this ground of rejection is justified. Such action is accordingly requested.

Claims 1-6, 10-18, and 39 are rejected under 35 U.S.C. §102(a) as anticipated by Masure *et al.* (WO 97/41151). Claims 1-6, 10-18 and 39 are also rejected under 35 U.S.C. §102(a) as anticipated by Briles *et al.* (WO 97/09994) and Claims 1, 4, 6, 10-14, 18 and 39

have been rejected under 35 U.S.C. §102(a) as anticipated by Hammerschmidt *et al.* (*Molecular Microbiology*, 1997). As these rejections appear to be based on a common theme, and to that extent, Applicants offer the following comments in response. Accordingly, as the rejections may pertain to the claims, particularly as amended, they are believed to be without merit and should be withdrawn.

The Examiner observes that the terminology in the claims is such as to permit a broad and ostensibly unrestrained, interpretation of the scope of the claimed invention in relation to the prior art. Specifically, the Examiner indicates that claims to the choline binding protein A truncates, without more, are readable on the disclosures of the references, as the former are contended to lack sufficient structural definition. In fact, the Examiner states that the instant claims are interpreted as properly subject to citation of teachings as to the full length protein that incidentally recite inclusion of fragments and the like, on the basis that (1) the present truncates are indistinguishable from the materials of the references, and that individual regions of the referenced materials contain common sequences common to those claimed herein; and (2) that the claim language lacks sufficient distinguishing structure, and that the requisite definitional basis for any structural distinctions presented is lacking. Both assertions overlook certain factual and legal points that are believed to reside in applicants' favor.

The truncates of the present invention are not merely abbreviated versions of the materials disclosed in the cited references, that can be prepared with facility, expedition and minimal forethought with the assurance that the desired activity of the larger molecule will still be present. In fact, the determination of the exact location for the severance of the molecules to arrive at the present truncates was purely arbitrary and gave no assurance that the desired protective effect sought in the final molecule when incorporated into a vaccine would be present. In fact the data presented in the Examples herein demonstrates that such unexpected effects were evident.

In particular, the removal of the choline binding domain in SEQ ID NO. 25 of Masure et al., three of which inventors are common to the present invention, is expected to yield improved protection. However, it is the removal of regions of the non-choline binding domain that could not be foretold by the art, as to which region thus removed would leave the molecule that remains with its protective activity intact. There is no prior teaching in Masure et al., or in any of the references of record, that provides such guidance and that consequently, enables the artisan to arrive at the invention. Simply stated, the demonstration

of protective effect by the present truncates is both surprising and unpredictable, and is consequently supportive, under the present law, of the attribution of patentability to the new materials. There is therefor neither anticipation nor suggestion in any of the references of record, that the present truncates could be prepared with the sequences and motifs disclosed and claimed herein, that would demonstrate the activities claimed herein. On this first basis, therefore, the references of record are distinguished, and the rejections should be withdrawn.

With respect to the terms appearing in the claims, these are appropriate as the materials to which they refer are not disclosed or suggested anywhere in the art. Thus claims that contain the phrase “comprising” still require the presence of the novel and unobvious truncates of the present invention, and as discussed above, such truncates are not provided merely by including the molecules disclosed in the references. Thus although the claims have been amended, the scope of the claims is submitted to be unchanged in that it properly focuses on the novel truncates that are at the heart of the invention. Turning to the claims and to the terms presented therein, all of the terms in question find ample definitional and exemplary support in the specification as filed, from such terms as ‘variants’, ‘fragments’, ‘mutants’, ‘analogs’ and others, so that the artisan is not left to speculate as to Applicants’ intent and scope. For example, the term analogs is defined in the specification at page 19, lines 21-24. The Examiner is referred to the specification, from page 6 through to page 22 for ample description that provides both definition and explanation conforming to the statute.

Lastly, the claims as amended focus on the truncates and refer to particular sequence information so as to assure that the claims thus stated are definite. Moreover, activities either explicitly claimed or exempted are not inherent in the claimed truncates and their related materials, as these materials themselves are novel and their activities are not and would not be previously known or expected.

In summary, the foregoing amendments and remarks are believed to overcome the rejections and objections of record, and withdrawal thereof is requested.

Fees

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account no. 11-1153 for any underpayment, or to credit any overpayments.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the

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file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,


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